

EXHIBIT 1

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

AZIYO BIOLOGICS, INC.,

Plaintiffs,

v.

NAVIGATORS SPECIALTY
INSURANCE COMPANY and
MCGRUFF INSURANCE SERVICES,
INC.,

Defendants.

C.A. No. N22C-09-_____ CCLD

**TRIAL BY JURY OF
TWELVE DEMANDED**

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COMPLAINT

Plaintiff Aziyo Biologics, Inc., by and through its attorneys, for its Complaint against Defendants Navigators Specialty Insurance Company and McGriff Insurance Services, Inc., hereby alleges upon knowledge as to itself and upon information and belief as to all other matters, as follows:

NATURE OF THE ACTION

1. Aziyo Biologics, Inc. (“Aziyo”) seeks declaratory relief concerning its contractual right to insurance coverage under an excess insurance policy (the “Navigators Policy”) that Defendant Navigators Specialty Insurance Company (“Navigators”) issued to Aziyo, attached as **Exhibit A**.

2. Aziyo additionally seeks damages arising from Navigators’ breach of contract and breach of the duty of good faith and fair dealing.

3. Aziyo also seeks damages arising from its insurance broker McGriff

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Insurance Services, Inc.’s (“McGriff”) breach of contract, negligence, and negligent misrepresentation stemming from its failure to procure adequate insurance coverage for Aziyo.

4. Specifically, an actual controversy exists between Aziyo and Navigators concerning the parties’ rights and obligations under the excess Navigators Policy to provide coverage to Aziyo for claims alleging personal injury from exposure to tuberculosis allegedly contaminating products manufactured, sold, or distributed by Aziyo or any of its subsidiaries, affiliates, or related entities entitled to coverage under the Navigators Policy. Navigators has previously taken the position that no coverage is owed under the Navigators Policy because damages caused by bacteria are excluded. An actual controversy therefore exists.

5. An actual controversy also exists between Aziyo and McGriff concerning McGriff’s failure to procure a products liability policy that reflects the mutual intent of the parties (as well as the intent of Aziyo as specifically communicated to McGriff) that would indisputably apply to Aziyo’s foreseeable product liability risks.

6. Aziyo is a life sciences company that produces biomedical products, including FiberCel Fiber Viable Bone Matrix (“FiberCel”), a human tissue product that is implanted in patients after spinal surgery in order to help their cells regenerate.

7. One of the known risks of the FiberCel product, as set forth in the product's instructions for use, is that "[c]urrent technologies may not preclude the transmission of infectious agents or disease."

8. Aziyo needed products liability coverage that would cover this known risk. Aziyo accordingly retained McGriff, an insurance broker which touts its ability to "find the best coverage for your unique needs," to procure this specialized coverage. Among other specifications, Aziyo requested that McGriff identify insurance coverage without any exclusions related to bacterial infection, and McGriff agreed to do so. In retaining and continuing to utilize McGriff, Aziyo relied on McGriff's stated experience, knowledge and expertise required to place products liability for a life sciences company like Aziyo.

9. McGriff procured primary coverage from CNA Insurance Company for the 2020-21 policy year that specifically provided such coverage (and, indeed, CNA is currently providing defense and indemnity coverage in connection with the FiberCel claims discussed in this Complaint).

10. McGriff also procured excess coverage for the 2020-21 policy year that was intended to provide such coverage; and McGriff informed Aziyo that the excess policy would provide the requested coverage.

11. McGriff approached Navigators, which is one of a small subset of

insurance carriers that offers product liability coverage expressly tailored to cover product liability risks faced by life sciences companies like Aziyo that produce biomedical products for human implant. In particular, Navigators utilizes a specially designed life sciences form that, *inter alia*, eliminates an exclusion that purports to exclude coverage for liability arising out of exposure to fungi or bacteria. This coverage will be referred to as the BioMedical-Specific Coverage.

12. Navigators was aware that McGriff was approaching Navigators to provide BioMedical-Specific Coverage specially designed to cover product liability risks inherent in Aziyo's human tissue implant products. Navigators also knew that McGriff would not have approached Navigators but for the availability of BioMedical-Specific Coverage.

13. Navigators agreed to provide BioMedical-Specific Coverage. Navigators knew that McGriff would not have bound Aziyo's coverage with Navigators, and instead would have procured BioMedical-Specific Coverage from another specialty insurer if Navigators did not offer this coverage.

14. Navigators intended to provide such coverage. However, due to an error by its underwriters, Navigators quoted coverage that referenced the incorrect policy form. The incorrect policy form included a bacteria exclusion that none of the parties – not Navigators, not McGriff, and not Aziyo – intended to be included

in the policy. At no time did Navigators inform McGriff that the quoted coverage contained a bacteria exclusion, and Navigators itself believed at the time the policy was issued, and for more than a year after the policy was issued, that such an exclusion was not present in the policy.

15. McGriff did not catch Navigators' error, nor did McGriff inform Aziyo of the error. As a result, the Navigators Policy was issued using a form that did not reflect the mutual intent of the parties that Navigators would provide BioMedical-Specific Coverage.

16. Unfortunately, in 2021 one batch of FiberCel allegedly became contaminated with a bacterial infection due to a donor having tuberculosis. Although Aziyo immediately recalled the batch, it had already been implanted in patients. This has led to scores of product liability claims asserting exposure to and bodily injury from tuberculosis allegedly in the FiberCel batch.

17. As noted, CNA is providing primary coverage for these claims. However, months after participating with CNA, Aziyo and Aziyo defense lawyers in developing comprehensive strategies for the defense and settlement of these FiberCel claims, Navigators discovered that its policy mistakenly included a bacteria exclusion. Navigators has leapt on this mistake to deny coverage, and it is now refusing to provide the more than \$15 million that will be imminently needed by

Aziyo to defend and/or settle FiberCel claims.

18. At the time when it needs assistance from its insurer, Aziyo has been abandoned and forced to file this lawsuit to secure the coverage it is properly owed.

PARTIES

19. Plaintiff Aziyo Biologics, Inc. is currently, and since at least 2015 has been, a corporation duly organized and existing under the laws of the State of Delaware. Aziyo maintains its principal place of business at 12510 Prosperity Drive, Suite 370, in Silver Spring, Maryland.

20. On information and belief, Defendant Navigators Specialty Insurance Company is a corporation duly organized and existing under the laws of the State of New York and maintains its principal place of business in Hartford, Connecticut. Navigators is authorized to, and does, conduct business in the State of Delaware and has written liability insurance policies with respect to risks located in Delaware and with respect to policyholders (including Aziyo) incorporated in Delaware.

21. On information and belief, Defendant McGriff Insurance Services, Inc. is a corporation duly organized and existing under the laws of the State of North Carolina and maintains its principal place of business in Charlotte, North Carolina. McGriff conducts business in the State of Delaware and has contracted to procure liability insurance policies with respect to risks located in Delaware and with respect

to policyholders (including Aziyo) incorporated in Delaware.

JURISDICTION

22. This Court has subject matter jurisdiction pursuant to Article IV, § 7 of the Delaware Constitution and 10 *Del. C.* § 541. This case is properly designated for the Complex Commercial Litigation Division (“CCLD”) because the amount in controversy exceeds one million dollars on account of (a) past, present and future FiberCel litigation costs far in excess of that amount that Aziyo has incurred or will incur; and (b) the availability of \$15 million in unexhausted limits provided by the Navigators Policy.

23. This Court has personal jurisdiction over Defendant Navigators because Navigators is authorized to sell or write insurance in Delaware, has conducted business within the State of Delaware, and/or has contracted to insure a risk located in Delaware. Further, Navigators has consented to the jurisdiction of this Court by contract provision in the Navigators Policy. *See* Ex. A at 8.

24. This Court has personal jurisdiction over Defendant McGriff because McGriff has conducted business within the State of Delaware and has contracted to procure insurance for a company incorporated in Delaware.

25. The parties presently disagree regarding the present and future extent of Defendants’ obligations to Aziyo regarding the FiberCel Claims. Thus, this Court

has the power to declare the parties' rights and obligations under 10 *Del. C.* §§ 6501, *et seq.*

FACTUAL BACKGROUND

I. AZIYO'S BUSINESS

26. Aziyo is a life sciences company that produces and distributes medical tissue products designed for human implantation. Aziyo uses natural materials to create products that are implanted during certain types of surgeries in order to help the site-specific cells to regenerate and the tissue to heal.

27. At the time Aziyo purchased the excess coverage from Navigators, its principal business was manufacturing and distributing FiberCel, a fiber-based bone repair product made from human tissue intended for use in orthopedic/spinal repair.

28. Aziyo's other products include cell removal technology that produces undamaged extracellular matrices for use in soft tissue reconstruction and biological envelopes that remodel into vascularized tissue into which electronic cardiac devices can be placed. Aziyo's products are used in cardiac and vascular surgery, neonatal and infant cardiovascular repair, and plastic surgery.

29. As a result, one of the principal product liability risks faced by Aziyo is the low but existent possibility that patients will receive implants of tissue products containing pathogens or other contaminants. Patients who receive such

implants may be at risk of serious bodily harm.

II. PURCHASE OF THE NAVIGATORS POLICY

30. In 2015, Aziyo retained McGriff as its insurance broker to procure appropriate products liability coverage with respect to potential risks associated with its business (“BioMedical-Specific Coverage”). At all times during the procurement of the Navigators Policy, McGriff was Aziyo’s insurance broker.

31. At all relevant times and as an essential requirement of being able to perform its professional brokerage duties, McGriff has known the general and specific nature of Aziyo’s life sciences business, which includes the production and distribution of medical human tissue products for implantation in humans.

32. McGriff represented to Aziyo that it had appropriate experience, knowledge and expertise required to place products liability for a life sciences company like Aziyo and to procure appropriate BioMedical-Specific Coverage, and McGriff assured Aziyo that it would obtain appropriate BioMedical-Specific Coverage to protect Aziyo from exposures arising from its life sciences business.

33. Aziyo relied on these representations when choosing to retain McGriff, and it relied on McGriff’s stated expertise in choosing appropriate insurers and policies. McGriff was aware of and intended such reliance by Aziyo.

34. Aziyo requested McGriff to advise on the appropriate and prudent level

of insurance coverage need to protect Aziyo from enterprise-threatening liability due to products liability exposure. McGriff advised Aziyo that a \$25 million total tower of liability coverage, including BioMedical-Specific Coverage, would be adequate for the risk inherent to its business.

35. In the Fall of 2020 and early 2021, McGriff procured primary liability coverage (including products liability coverage) from Continental Casualty (“CNA”) with limits of \$10 million that is applicable to claims arising from alleged bacterial infection. CNA’s policy is a “Life Sciences Liability” policy with specific endorsements relevant to the life sciences industry. This coverage contained BioMedical-Specific Coverage.

36. Aziyo requested additional products liability coverage beyond primary limits, and McGriff agreed to procure appropriate follow-form excess coverage to this life sciences policy. McGriff contacted Navigators to place this excess layer with a policy limit of \$15 million.

37. McGriff and Navigators communicated extensively about Aziyo’s type of business, products, and insurance needs, and Aziyo’s need for BioMedical-Specific Coverage. Aziyo submitted an extensive application detailing its products and potential risks.

38. Communications between McGriff and Navigators from the Fall of

2020 and early 2021 show that Navigators’ underwriter, Jeff Prather, studied the Aziyo website and understood that both Aziyo Biologics and its subsidiary, Aziyo Med, LLC (“Aziyo Med”), manufactured human tissue products.

39. When Navigators sent its proposal for insurance for the first-layer excess products liability policy, McGriff advised Aziyo to purchase the policy. In doing so, McGriff believed and so informed Aziyo that the Navigators policy included BioMedical-Specific Coverage. McGriff intended that Aziyo rely on this representation, and Aziyo did so by agreeing to purchase the Navigators Policy in the amount recommended by McGriff.

III. THE CNA AND NAVIGATORS POLICIES

40. CNA issued primary layer “Life Sciences Liability” policy no. ADT 6079208689 for the policy period of Nov. 1, 2020 to Nov. 1, 2021, with an aggregate limit of \$10 million (the “CNA Primary Policy”).

41. The CNA Primary Policy has no fungi or bacteria exclusion.

42. The CNA Primary Policy is followed by the first-layer excess products liability policy no. GA20LEX0BITTJNC issued by Navigators for the Policy Period, which provides \$15 million of coverage in excess of the \$10 million in underlying limits.

43. Except as otherwise expressly provided, the Navigators Policy “follows

form” to the terms and conditions of the CNA Primary Policy, meaning that it adopts the terms and conditions as if fully set forth in the CNA Primary Policy.

44. The Navigators Policy states that if any inconsistency or contradiction exists between an exclusion of Navigators’ Policy and an exclusion of the controlling underlying insurance, the exclusion of the Navigators Policy will apply.

45. The Navigators Policy enumerates a number of exclusions, including damages that arise out of “the actual, alleged, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of fungi or bacteria.”

46. Fungi is a defined term. Its definition includes the statement: “But fungi does not include any fungi that are, are on, or are contained in a good or product intended for human consumption.” Ex. A at p. 3 of 10.

47. Bacteria is not defined in the Navigators Policy.

48. The limits of both the CNA and Navigators Policies are eroded by damages and defense costs arising out of claims against Aziyo from patients who allege they received contaminated tissue samples and have suffered resulting harm.

49. Aziyo and Navigators also agreed to a Change Endorsement effective January 1, 2021 in which several changes were made to the Navigators Policy (the “Change Endorsement”). These changes include adding Aziyo Med, LLC, Aziyo’s

subsidiary, to the Navigators Policy and adding some exclusions including for damages “arising out of” various named diseases including HIV/AIDS, Zika virus, West Nile virus, Ebola, and Viral Hepatitis. Tuberculosis was not listed as a named disease. This Change Endorsement is attached as **Exhibit B**.

50. The Change Endorsement stated that it “modifies insurance provided under the following: GLS Elite Products – Completed Operations Liability Coverage.” Ex. B at 1 of 1.

IV. NAVIGATORS’ LIFE SCIENCES FORM

51. Navigators is a subsidiary and brand of The Hartford that offers specialty and niche insurance for hard-to-place risks. It is one of a small handful of insurers that offers policies specific to the risks present in the life sciences industry.

52. For the non-life sciences market, Navigators offered coverage on a policy form that expressly excludes liability arising out of “the actual, alleged, threatened, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of fungi or bacteria.”

53. By contrast, its life sciences form contained a modified version of that same fungi and bacteria exclusion with a carve-out for goods or products “**intended for bodily consumption**.” This form is titled “GLS Elite Products – Completed Operations Liability Coverage,” form number NAV LSP 200 01 16, and is attached

as **Exhibit C**. This form was available through the entire period that McGriff was Aziyo's broker.

54. This life sciences form modifies the standard products liability policy language in key ways that reflect the nature of the life sciences business. Most importantly here, it adds a clause to the fungi or bacteria exclusion section, stating. "This exclusion does not apply to any fungi or bacteria that are, are on, or are contained in, a good or product intended for bodily consumption."

55. McGriff was aware that Navigators offered this specialized life sciences coverage. Based on this knowledge, McGriff contacted Navigators to provide coverage to Aziyo.

56. Navigators was aware that McGriff was contacting Navigators specifically because Navigators offered coverage through its life sciences form for companies like Aziyo. Navigators also agreed to provide such life sciences coverage, and it knew that McGriff would not have placed coverage with Navigators unless Navigators utilized the life sciences form. At all times, there was a mutual intent between Aziyo (through its broker, McGriff) and Navigators that Navigators would issue the Navigators Policy using the life sciences form.

57. However, when Navigators issued its proposal for coverage and later the binder, the *non*-life sciences form number was mistakenly listed on the forms.

McGriff did not realize that the wrong form number was listed.

58. This mistake carried forward when Navigators issued the actual policy, about a month later, and the wrong form was included in the policy.

59. When Navigators issued the full policy, McGriff employees reviewed the policy. None of them noticed the lack of the carve-out for bodily products intended for human consumption. As a McGriff employee later stated in a call, “[b]etween us we have one hundred years of combined experience and this just got missed. All three of us missed that something changed on the wording of the policy.”

60. McGriff failed to notice this mistake prior to policy placement, at the time of policy placement, or for many months thereafter. It was not until Aziyo was embroiled in products liability litigation that McGriff discovered its mistake.

61. McGriff was aware that Aziyo was relying on McGriff to review the Navigators Policy to ensure that it contained the prior coverage, and McGriff accepted the responsibility to conduct this policy review.

V. THE UNDERLYING FIBERCEL LITIGATION

62. In June 2021, Aziyo became aware that one lot of its orthopedic/spinal repair product FiberCel, consisting of 154 units, had been inadvertently contaminated with tuberculosis bacteria due to an infected donor, despite the Company’s diligence in following all applicable safety protocols. Although Aziyo

immediately recalled the lot, it had already been shipped to facilities in 20 states and had been implanted in at least 113 patients during spinal fusion operations.

63. To date, at least 98 claims have been asserted against Aziyo alleging injury, including the development of tuberculosis and three patient deaths (the “FiberCel Litigation”). Other injuries may require medical treatment, although are less severe. Other patients have alleged the need for medical monitoring, although the patients are currently in good health.

64. More claims are anticipated.

VI. AZIYO NOTIFIES ITS INSURERS OF THE FIBERCEL CLAIMS

65. Aziyo immediately notified CNA and Navigators of the claim in June 2021. On June 17, 2021, Navigators responded with an acknowledgment letter reserving its rights and assigning Claims Officer Thomas Morelli to Aziyo’s claim.

66. Beginning on June 14, 2021 (before the date of the acknowledgement letter) and continuing for seven months thereafter, Navigators participated in the defense of the FiberCel Litigation. During this seven-month period, Mr. Morelli exchanged and reviewed correspondence and joined strategy calls with necessary parties that included Aziyo representatives, the CNA claims adjuster, and defense counsel for the underlying FiberCel Litigation.

67. Navigators was intimately involved in helping direct the defense of the

FiberCel Litigation and provided significant input to Aziyo's defense counsel. The specific strategies that were agreed upon are confidential; but Aziyo will establish that if Navigators had not been actively participating in the development of such strategies and given every indication that its \$15 million coverage would be available to implement that strategy, then Aziyo and its defense counsel would have embarked on a radically different strategy. Aziyo has incurred millions of dollars and changed its litigation posture in reliance upon Navigators' months-long participation in strategic decision-making and in reliance on Navigators' representations that Aziyo would have access to the \$15 million limits of the Navigators Policy. Navigators specifically intended that Aziyo would rely on Navigators' words and conduct.

68. However, without any warning, on January 26, 2022, Navigators sent a letter to Aziyo "updating" its position and stating that there was no coverage for the FiberCel Litigation claims under the Policy due to the fungi and bacteria exclusion. Navigators offered no explanation for why this defense was being asserted for the first time seven months after Aziyo first notified Navigators of its claim.

69. Navigators also informed Aziyo that it no longer would participate in the mediation that the parties had planned in March of 2022. As a result, the mediation had to be cancelled because the mediators refused to go forward without assurance that there would be sufficient funds to settle the claims. As a result of this

delay, Aziyo incurred significant additional defense costs.

70. Aziyo has incurred substantial costs to defend the FiberCel Litigation and in connection with mediation and settlement efforts. Due to the seriousness of the alleged harm and the numerosity of claims, it is virtually certain that the limits of the CNA primary layer will be exhausted.

71. Aziyo's damages may include not only the \$15 million policy limit intended to be provided by the Navigators Policy, but also any defense costs and liability Aziyo incurs in excess of the intended Navigators limit due to its detrimental reliance on Navigators' conduct and refusal to participate in mediation and the need to significantly alter a strategy that Navigators helped to craft.

VII. REFORMATION IS APPROPRIATE DUE TO MUTUAL MISTAKE

72. Navigators issued an excess layer Policy that followed form to the CNA Primary Policy, with a few enumerated exceptions. One of these exceptions was the "fungi or bacteria exclusion." The CNA Primary Policy did not contain any such exclusion.

73. The inclusion of the "fungi or bacteria exclusion" in the Navigators Policy was a mutual mistake and does not reflect the actual agreement between the parties, which was to follow form to CNA's underlying third-party liability policy and provide BioMedical-Specific Coverage to Aziyo for claims stemming from

bacteria if the products were intended for bodily consumption.

74. Aziyo intended to purchase a policy that followed the CNA Primary Policy and that provided BioMedical-Specific Coverage specific to the risks of a life sciences company. It believed it had done so, and accordingly paid a higher premium than it would have if it had attempted to purchase a policy containing a bacterial or fungi exclusion.

75. McGriff also intended to procure BioMedical-Specific Coverage for Aziyo from Navigators and intended that the Navigators Policy would include the correct life sciences liability form. McGriff's specific intent was communicated on multiple occasions to Navigators during the procurement process and was inherent in its approach to Navigators as one of the only companies offering BioMedical-Specific Coverage.

76. On February 18, 2022, McGriff wrote to Navigators appealing its decision to deny coverage, saying, "We contend that this form was incorrectly attached to this policy. The correct form that was requested, and should have been attached to the Aziyo policy, is the GLS Elite Products-Completed Operations and Professional Liability Coverage (NAV LSP PPL DEC 07 18) in which contains substantially different verbiage in Exclusion 6. Fungi or Bacteria."

77. On August 16, 2022, McGriff counsel Anthony Tatum wrote to

Navigators, stating “[T]here was mutual mistake in issuing the Policy with the Fungi and Bacteria Exclusion (as interpreted by Navigators) without the express exception that, for both fungi and bacteria, the exclusion does not apply to consumable products. The parties understood and expected that the Navigators Policy would follow form to the underlying CNA policies.”

78. Navigators also intended to provide such BioMedical-Specific Coverage including its life sciences form, as evidenced by its awareness that it was being approached only because it offered such coverage, its agreement to issue such coverage, its issuance of the Navigators Policy at a premium reflecting coverage for such risks, and its post-issuance conduct, all as set forth in this Complaint.

79. On information and belief, Navigators also believed that it had issued BioMedical-Specific Coverage including the life sciences form. Evidence for this includes but is not limited to:

- a. The Change Endorsement dated January 1, 2021 stated that the insurance policy being modified was the “GLS Elite Products – Completed Operations Liability Coverage” – the title of the life sciences form with the bodily consumption carve-out. Ex. B.
- b. The Change Endorsement also amended the language of the Navigators Policy to include a “Modified Designated Products

Exclusion Endorsement” which excluded certain specific named diseases, including HIV/AIDS, TSE, Zika virus, Ebola, and Viral Hepatitis. Tuberculosis is not one of these named diseases. Such an endorsement would not have been necessary if Navigators believed its policy contained the fungi and bacteria exclusion.

- c. At the time of underwriting, the subject line of the majority of emails between McGriff and Navigators was “Aziyo – Soft Tissue Agreement,” implying that they were negotiating the BioMedical-Specific Coverage.
- d. Navigators was aware that Aziyo was a life sciences company whose main business is creating medical products intended for human implantation. During the process of applying for coverage, Aziyo filled out a lengthy and detailed application. Navigators also reviewed Aziyo’s website. Aziyo, moreover, has publicly acknowledged its business’ risk: FiberCel’s instructions for use warn that “[c]urrent technologies may not preclude the transmission of infectious agents or disease.”
- e. Communications ahead of the November 2021 renewal demonstrate that Navigators charged a 21% increase in premium

and made changes to the Policy, including adding a Contaminants/Communicable Disease Exclusion, because it believed there was coverage for the FiberCel Litigation claims under the 2020-21 Navigators Policy.

80. There was a mutual mistake as to the form number listed in the policy quote. This mistaken form number carried over to the binder and, ultimately, to the issued policy.

81. Navigators should not be permitted to benefit from this windfall and keep Aziyo's premiums in exchange for an essentially worthless policy, especially after indicating that it would provide coverage for seven months and causing Aziyo to rely on that representation to its detriment.

VIII. NAVIGATORS BREACHED ITS CONTRACTUAL OBLIGATIONS

82. Even though Aziyo believes that the form issued by Navigators is a mistake, McGriff has advised Navigators of McGriff's view that there is still coverage under the Policy as issued.

83. Specifically, the language of the exclusion and its related definition makes clear that it was not intended to exclude products and goods intended for bodily consumption.

84. The Policy contains a sequential group of three pollution-related

exclusions for asbestos, fungi or bacteria, and silica or silica related dust. Each of these exclusions contains a defined term which, when read with the rest of the language of the exclusion, clarifies what is intended to be excluded.

85. The fungi and bacteria exclusion relates to liability “arising out of . . . the existence or presence of fungi or bacteria.” In the Navigators Policy, fungi is a defined term but bacteria is not.

86. The definition of fungi states that fungi “does not include any fungi that are, are on, or are contained in *a good or product intended for human consumption.*” Ex. A at PDF pg. 15. There is no standalone bacteria exclusion in the policy, but rather fungi and bacteria are intentionally grouped together. Therefore, McGriff has explained to Navigators that the only reasonable reading of the exclusion is that it does not apply to “fungi *or bacteria*” that is contained in any “good or product intended for human consumption.”

87. In addition, Navigators was aware of the particulars of Aziyo’s business and the products it manufactured. It knew that issuing a “follow form” excess products liability policy with a broad bacteria exclusion but no human products carve-out would vitiate all or a significant portion of the third-party liability bodily injury coverage that Aziyo expected, rendering the policy illusory.

88. Aziyo has complied with all of its requirements under the policy. Aziyo

has provided notice of the pendency of the FiberCel Litigation claims to Navigators and has periodically provided Navigators with status reports concerning its defense.

89. All prerequisites to attachment of the excess Navigators Policy have been or will soon be met.

90. Therefore, Navigators is obligated to (a) defend or pay for the defense of Aziyo and/or (b) indemnify Aziyo, including the funding of settlements, in connection with the FiberCel Litigation, upon the attachment of the excess Navigators Policy.

91. Aziyo is entitled to all benefits provided by the Navigators Policy.

92. The FiberCel Litigation is covered under the Navigators Policy.

93. Aziyo has incurred and will continue to incur substantial defense and indemnity costs in connection with the FiberCel Litigation. Upon exhaustion of the limits of liability directly underlying the Navigators excess layer, coverage is or will be available under the Navigators Policy.

94. In anticipation of attachment, Aziyo has previously sought confirmation from Navigators that it will fulfill its obligations under the Policy. To date, Navigators has not acknowledged its obligations to (a) defend or pay for the defense of Aziyo and/or (b) indemnify Aziyo, including the funding of settlements, in connection with the FiberCel Litigation, upon attachment of the Navigators Policy

and has previously indicated that it does not believe coverage is provided.

95. Because Navigators has previously disputed its impending coverage obligations to defend or pay to defend and indemnify Aziyo in connection with the FiberCel Litigation, an actual and justiciable controversy exists.

96. Navigators' failure to commit to honoring its obligations will require Aziyo to bear the costs incurred for the defense and settlement of the FiberCel Litigation claims.

97. Aziyo has incurred and will continue to incur reasonable attorneys' fees and costs to pursue this coverage action as a result of Navigators' breach.

98. All of the conditions of the Navigators Policy have been or will soon be met.

99. Attachment of the Navigators Policy occurred or will soon occur.

**IX. MCGRIFF'S NEGLIGENCE AND BREACH OF CONTRACT
CAUSED AZIYO TO SUFFER HARM**

100. Navigators is unlikely to be a willing and timely source of meaningful financial contribution to a mediated settlement. Had McGriff caught the placement mistake in the Navigator's excess coverage in a timely manner, Aziyo would now have the full amount of the Navigators' Policy available for settlement efforts.

101. As Navigators' insurance broker, McGriff had the duty to exercise such reasonable skill and ordinary diligence as may fairly be expected from a person in

his profession or situation, in doing what is necessary to effect a policy, in seeing that it effectually covers the property to be insured, and in selecting the insurer.

102. McGriff was negligent in advising Aziyo that it only needed \$25 million in coverage. McGriff was also negligent in failing to notice that the proposal for insurance and binder had the wrong form number listed. McGriff was also negligent in failing to notice the mistaken form included in the Navigators Policy.

103. Regardless of whether the Navigators Policy is ultimately reformed, McGriff was negligent when it advised Aziyo to purchase the Navigators Policy when it contained an exclusion that arguably denied coverage for Aziyo's fundamental core business.

104. Aziyo reasonably relied on this statement when purchasing the Navigators Policy.

105. McGriff knew Aziyo would rely on this statement when purchasing the Navigators Policy, and intended Aziyo to so rely.

106. By failing to procure the appropriate and requested coverage, and by representing that it had done so when it fact if procured a policy that did not contain the appropriate language, McGriff has violated its duties as a licensed insurance broker to acquire appropriate, effective coverage.

107. McGriff is responsible for Aziyo's damages—not only for the \$15

million coverage limit Aziyo should have had from Navigators, but also Aziyo's damages from losing a reasonable settlement opportunity and having to proceed to trials for many of the claims that have been brought. McGriff is also responsible for the foreseeable economic damages, including the sums incurred by Aziyo in having to pursue this action to address a claims denial by Navigators that never would have occurred but for McGriff's negligence and breach of contract.

**COUNT ONE: REFORMATION OF CONTRACT
AGAINST NAVIGATORS**

108. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

109. Aziyo and Navigators agreed that Navigators would issue the life sciences policy form that followed CNA's life sciences liability policy and provided coverage for the risks inherent to products involving human tissue.

110. Navigators was aware that Aziyo is a life sciences company that creates products intended for bodily consumption, products that contain the inherent risk of bodily injury caused by bacteria.

111. Aziyo was aware that Navigators provided a specialty coverage form for life sciences companies, and McGriff reached out to Navigators for that reason.

112. Both Aziyo and Navigators believed that Navigators had issued that life sciences form, and acted consistent with that belief for years.

113. Rather than point to the exclusion when Aziyo first filed the claim, Navigators participated in strategic discussions and indicated that it would cover costs for seven months.

114. In the Change Endorsement, Navigators referred to Aziyo's policy by the name of the life sciences product. *See* Ex. B.

115. There was a mutual mistake in the form number listed in the policy quote and binder, which resulted in the wrong form being issued.

116. Navigators is now unjustly benefitting from that mistake, denying coverage that both parties understood to be the point of the insurance Policy.

117. The contract should be reformed to reflect the intent of the parties.

**COUNT TWO: DECLARATORY JUDGMENT
AGAINST NAVIGATORS**

118. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

119. Aziyo is the insured under the Policy.

120. Navigators is the insurer that issued the Policy.

121. Aziyo has sustained and incurred losses arising from the FiberCel Litigation, including substantial defense costs, which are covered by the Policy and for which Aziyo has not received payment in full.

122. Even though the allegations of the FiberCel complaints fall within the

coverage granted by the Policy, and even though Navigators has acted as if it has a duty to defend and previously made statements acknowledging that fact, Navigators continues to refuse and/or fail to defend Aziyo in the FiberCel Litigation.

123. An actual and immediate controversy exists between Aziyo and Navigators with respect to Navigators' duties and obligations to defend and/or indemnify Aziyo under the Navigators Policy because Aziyo has requested a defense from Navigators, including payment of past, present, and future defense costs, and Navigators has refused to acknowledge its duties and has failed to pay Aziyo fully for its defense costs.

124. Aziyo seeks a judicial determination of the rights and duties of Aziyo and Navigators with respect to an actual controversy arising out of the Navigators Policy. Specifically, Aziyo seeks a judicial determination that the fungi and bacteria exclusion does not apply.

125. The issuance of declaratory relief by this Court will terminate some or all of the existing controversy among the parties.

COUNT THREE: BREACH OF CONTRACT AGAINST NAVIGATORS

126. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

127. There is a contract between Aziyo and Navigators whereby Aziyo pays

certain premiums and Navigators pays for or indemnifies Aziyo's costs incurred under a third-party liability insurance policy.

128. Aziyo has fulfilled all of its contractual allegations, including but not limited to paying all of its premiums and providing timely notice of its claim.

129. Aziyo's defense and settlement costs are covered under the Navigators policy. The Navigators policy has attached or soon will attach.

130. Under the Policy, Navigators agreed to provide Aziyo insurance coverage pursuant to the terms and conditions of the Policy.

131. On numerous occasions, Aziyo requested a defense from Navigators.

132. Navigators refused and/or failed to acknowledge its duty to defend Aziyo, and has failed to pay Aziyo all those costs, losses, and expenses, including defense costs, that are covered under the terms of the Policy.

133. Navigators' failure to acknowledge its duty to defend Aziyo, to pay its full share of Aziyo's costs, losses, and defenses, including defense costs, and to pay future costs, including future defense costs, constitutes a material breach of the Policy, which breach is ongoing and continuous.

134. Aziyo has been damaged by Navigator's breach of the Policy in an amount no less than \$15 million.

135. Aziyo has also been damaged by the costs of pursuing this coverage

litigation against Navigators, as a result of Navigators' breach.

**COUNT FOUR: BREACH OF DUTY OF
GOOD FAITH AND FAIR DEALING
AGAINST NAVIGATORS**

136. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

137. Every contract, including the Policy, contains an implied covenant of good faith and fair dealing. The purpose of this duty is to ensure that parties do not take advantage of each other in a way that would not have been contemplated at the time the contract was drafted or do anything that will destroy the other party's right to receive the benefit of the contract.

138. Duties involving the exercise of good faith arise when one party is given broad discretion in performing its obligations under the contract. Where a contract specifically vests one of the parties with broad discretion in performing a term of the contract, the covenant of good faith and fair dealing requires that the discretion be exercised reasonably and with proper motive, not arbitrarily, capriciously, or in a manner inconsistent with the reasonable expectations of the parties.

139. Under the Policy, Defendant had discretion to perform its obligations under the contract. Defendant, however, excised its discretion unreasonably, with an improper motive, and in a manner that was arbitrary, capricious, and inconsistent

with the reasonable expectations of the parties, specifically, to arbitrarily reduce the amount of its payment to Aziyo.

140. If Navigators also believed that it had issued Aziyo the life sciences policy form, then its abrupt denial of coverage seven months later when it discovered the mistake was a bad faith attempt to take advantage of the mutual mistake for an unexpected windfall. This was a violation of the duty of good faith and fair dealing.

141. If it did not, then its active participation in the defense strategy of the FiberCel Ligation for seven months, causing Aziyo to incur significant costs in a strategy it would not otherwise have pursued, was a violation of the duty of good faith and fair dealing.

142. Navigators' breach of the covenant of good faith and fair dealing have caused damages to Aziyo in the amount of defense costs.

COUNT FIVE: DETRIMENTAL RELIANCE AGAINST NAVIGATORS

143. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

144. Navigators indicated that it would provide coverage up to the limit of \$15 million for defense and settlement of the FiberCel Litigation. It actively participated in strategy discussions for seven months and had significant input into the strategy to divide the claims into three tranches for mediation and to settle all of

the FiberCel claims.

145. Navigators also indicated that it would provide coverage when Aziyo's Policy was being renewed. In an email dated September 9, 2021 regarding Navigators' Conditional Renewal Notice, Navigators underwriter Jeff Prather stated that Navigators wanted to include a communicable disease exclusion in order to ensure that there was no "**additional coverage** (on future policies)" for the known FiberCel claims. He stated that this exclusion would "effectively batch all future claims into the policy where it was originally reported." Navigators also increased the premium for the renewed policy by 21% because of the FiberCel Litigation.

146. In another email, Navigator's Jeff Prather stated that his company was "on the hook" for the FiberCel claims.

147. Aziyo relied on these representations when it adopted its strategy. It would not have done so if it knew it only had the insurance proceeds from the CNA primary layer available to fund potential mediation.

148. Aziyo's relied on Navigators' representations to its detriment. It has pursued a very different strategy than it otherwise would have done and utilized a significant portion of the CNA policy limits implementing its strategy of shepherding FiberCel claims to mediation. It would never have adhered to this strategy if it had not believed that Navigators would provide coverage.

149. Navigators is now estopped from denying coverage under the policy because Aziyo has relied on its actions and statements to its detriment.

**COUNT SIX: BREACH OF CONTRACT
AGAINST MCGRIFF**

150. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

151. Aziyo retained McGriff as its insurance broker to procure appropriate products liability coverage with respect to potential risks associated with its business. Aziyo paid McGriff a commission accordingly.

152. Aziyo retained McGriff because of its stated expertise in procuring specialized coverage, including for life sciences companies.

153. Aziyo informed McGriff of the nature of its business and the risks attendant to a life sciences company.

154. However, McGriff breached this contract and failed to procure appropriate products liability coverage, instead procuring a policy that may not cover known serious risks associated with Aziyo's products.

155. As a result of this potential lack of excess insurance, Aziyo has suffered a loss in the amount of the \$15 million policy limit and any damages it suffers from the inability to reach a reasonable settlement as a result of not having access to excess insurance that should have been provided by Navigators. Further, even if the

Navigators Policy is ultimately deemed to provide coverage for the FiberCel Claims, McGriff's breach of contract resulted in, inter alia, the refusal of Navigators to provide coverage, disruption of Aziyo's ability to resolve the FiberCel Claims, and the need for Aziyo to engage in expensive coverage litigation against Navigators.

**COUNT SEVEN: NEGLIGENCE
AGAINST MCGRIFF**

156. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

157. As Aziyo's insurance broker, McGriff had the duty to exercise the reasonable care and skill of a professional insurance broker in procuring a policy that effectually covers the property to be insured.

158. McGriff breached this duty and did not procure coverage that clearly covers Aziyo's risk.

159. McGriff was negligent in advising Aziyo that it only needed \$25 million in coverage.

160. McGriff was negligent in failing to notice that the proposal for insurance and binder had the wrong form number listed.

161. McGriff was negligent in failing to notice that the mistaken form was included in the Navigators Policy.

162. In all cases, McGriff did not meet the standard of care that can

reasonably be expected of an insurance broker in a similar position.

163. As a result of McGriff's negligence, Aziyo suffered actual injury or loss. Aziyo not only does not presently have access to the \$15 million policy limit from Navigators, but it has also suffered increased litigation expenses due to the necessity of cancelling mediations due to lack of funds. Further, even if the Navigators Policy is ultimately deemed to provide coverage for the FiberCel Claims, McGriff's negligence resulted in, *inter alia*, the refusal of Navigators to provide coverage, disruption of Aziyo's ability to resolve the FiberCel Claims, and the need for Aziyo to engage in expensive coverage litigation against Navigators. McGriff is liable for these damages.

**COUNT EIGHT: NEGLIGENT MISREPRESENTATION
AGAINST MCGRIFF**

164. Aziyo repeats and re-alleges each and every allegation contained in each preceding numbered paragraph of this Complaint as if fully set forth herein.

165. As Aziyo's insurance broker, McGriff had the duty to exercise the reasonable care and skill of a professional insurance broker in procuring a policy that effectually covers the property to be insured.

166. Aziyo and McGriff had the kind of relationship where Aziyo had the right to rely on McGriff for information and McGriff had the duty to give correct information. Aziyo had retained McGriff to advise it on its insurance needs and to

help it choose and apply for insurance policies.

167. Aziyo and McGriff had discussed Aziyo's need for a products liability policy that would cover life sciences companies, specifically human tissue products implanted in patients after surgeries.

168. McGriff explained to Aziyo that the Navigators Policy would provide adequate third party products liability coverage for its business and that it would cover the risks that they had discussed.

169. McGriff also conveyed to Aziyo that \$25 million in total coverage would be sufficient.

170. In both cases, these statements turned out to be false. Navigators has denied coverage based on the fungi and bacteria exclusion, and even if Navigators had not denied coverage, Aziyo's liability threatens to be greater than \$25 million.

171. It was negligent for McGriff to make these misrepresentations. The Navigators Policy contains an exclusion for damages that arise out of "the actual, alleged, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of fungi or bacteria," and if McGriff should have noticed that.

172. McGriff intended that Aziyo would purchase the Navigators Policy based on its statement and that McGriff would earn a commission from the purchase.

173. McGriff knew and intended that Aziyo relied on this statement to purchase the policy and knew that if the coverage amount was not adequate, Aziyo would suffer loss or injury.

174. Aziyo justifiably relied on this statement when purchasing the Navigators Policy, as McGriff was its insurance broker and this statement was made in the context of advising Aziyo on which policy to purchase.

175. McGriff suffered damage as a result of Aziyo's negligent misrepresentation. Further, even if the Navigators Policy is ultimately deemed to provide coverage for the FiberCel Claims, McGriff's negligent misrepresentation resulted in, *inter alia*, the refusal of Navigators to provide coverage, disruption of Aziyo's ability to resolve the FiberCel Claims, and the need for Aziyo to engage in expensive coverage litigation against Navigators.

RELIEF SOUGHT

WHEREFORE, Aziyo respectfully requests judgment as follows:

A. Aziyo requests that the Court reform the contract due to mutual mistake and enter a declaratory judgment that the parties intended there to be a carve out in the fungi and bacteria exception for products intended for bodily consumption;

B. Aziyo requests that this Court enter a declaratory judgment in favor of Aziyo and against Navigators, declaring that pursuant to the terms of the

Navigators policy, the fungi and bacteria exception does not apply and Aziyo is entitled to coverage under the policy;

C. Aziyo also requests damages based on Navigators' breach of contract and breach of the duty of good faith and fair dealing in an amount to be proven at trial.

D. Aziyo also requests damage from McGriff based on its breach of contract, negligence, and negligent misrepresentation in an amount to be proven at trial.

E. Additionally, Aziyo requests such other and further relief as this Court may deem just and proper.

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DEMAND FOR TRIAL BY JURY

Aziyo hereby demands a trial by jury of twelve on all issues so triable.

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